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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,531	02/25/2005	Mitsuru Kuribayashi	MUR-046-USA-P	7067

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EXAMINER
DICKINSON, PAUL W

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,531	KURIBAYASHI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7 and 9-15* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 7 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/17/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 4/30/2010, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 4-5, 7, 9-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985; document already in record) is maintained.

The rejection of claims 1, 4-5, 7, 9-14 under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985) in view of Nowicki (Medicine & Science in Sports & Exercise, 2002) is maintained.

The rejection of claims 1, 4-5, 7, 9-10 and 13-14 under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985) in view of US 5682726 ('726) is maintained.

Applicant's arguments focuses on the following two points:

(1) The Examiner has concluded that the weight percent given for polyvinyl alcohol in EP '985 corresponds to the weight percent of nonionic synthetic polymer. The Examiner has concluded that the nonionic synthetic polymer component is the same as the polyhydric alcohol component. Claim 1 has been rewritten to specify the species of nonionic synthetic polymers and the species of polyhydric alcohols. The secondary references do not make up for the deficiency of EP '985.

(2) '726 does not perform the same function as the present application in that it teaches a method for forming an iontophoretic patch involving forming a laminate having a chamber between a first and second laminate and inserting an inert gas into said chamber. In contrast, in the present invention oxygen dissolved in the gel is positively removed by replacement with nitrogen and/or vacuum kneading at the time ingredients are added and kneaded.

Applicant's arguments have been fully considered but are not found persuasive for the following reasons:

Regarding (1), EP '985 discloses the following in paragraphs 19-28:

The adhesive gel may comprise an acidic polymer such as polyacrylic acid, which corresponds to Applicant's ionic synthetic polymer(s) (A).

Several disclosed nonionic synthetic polymers may be incorporated into the gel, including polyvinylpyrrolidone and polyvinyl alcohol as binders. The incorporation of

polyvinylpyrrolidone and/or polyvinyl alcohol corresponds to Applicant's nonionic synthetic polymer(s) (B).

The adhesive gel may comprise gelatin, which correspond to Applicant's naturally-occuring polymer(s) (C).

The adhesive gel may comprise a polyhydric alcohol such as polyethylene glycol, which corresponds to Applicant's polyhydric alcohol(s).

Further EP '985 teaches incorporation of a polyfunctional epoxy compound (a crosslinking agent), and a drug.

It would have been obvious to one of ordinary skill in the art to prepare an adhesive gel comprising the above components to afford an adhesive gel that allows a basic drug to be delivered effectively into an *in vivo* site via iontophoresis. It would have been further obvious to optimize the amount of the ionic synthetic polymer (A), nonionic synthetic polymer (B), naturally-occurring polymer (C), and polyhydric alcohol in the gel to achieve a pH of between 3 to 7 and improved efficacy of the drug. In this way, one would find the amounts disclosed in instant claims 1 through routine experimentation. EP '985 provides sufficient guidance to this end. EP '985 teaches that the polyacrylic acid (A) is added to adjust the pH and may be present from 1 to 20% by weight (see paragraph 23). EP '985 further teaches that polyethylene glycol (B) may be present in 10 to 60% by weight (see paragraph 26). EP '985 further teaches that the gelatin (C) (the naturally-occurring polymer) may be present from 0.1 to 15% by weight (see paragraph 28). These ranges fully overlap with Applicant's ranges in instant claim 2. These ranges also fully satisfy the equations $(B + C)/A \geq 1.5$ and $A + B + C \geq 7\%$ in

instant claim 3. If the maximum of each of these ranges is taken, then (B + C)/A = (60 + 15)/(20) = 3.8 ≥ 1.5 and A + B + C = 20 + 60 + 15 = 95% ≥ 7%. "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Regarding (2), '726 was relied on for its teaching that oxygen levels in iontophoresis compositions may be reduced by a number of techniques, including replacing oxygen with an inert gas such as nitrogen and/or incorporating an oxygen scavenger such as sodium metalsulphite (see col 3, lines 19-44; col 5, lines 1-11). The purpose of removing oxygen is to increase the stability and shelf life of the drug (see abstract). It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to remove oxygen from the adhesive gel of EP '985 by one of the techniques disclosed by '726. The art recognizes that removing the oxygen will result in a product with a longer shelf life. This would be especially important in the embodiment of EP '985 wherein ephinephrine is the drug, as '726 suggests such oxygen removal is particularly desirable for increasing the shelf life of iontophoretic compositions comprising ephinephrine. The oxygen removal techniques taught by '726 are not identical to the removal techniques in instant claim 14, the latter encompassing positively removing the oxygen by replacement with nitrogen and/or vacuum kneading at the time the ingredients are added and kneaded. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based

on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113. In the instant case, the same product will be made (i.e. an adhesive gel with decreased levels of oxygen) whether the oxygen is removed by the steps of '726 or the steps of instant claim 14. In other words, Applicant's adhesive gel which is deoxygenated by the method steps of instant claim 14 is indistinguishable from the adhesive gel of EP '985 which is deoxygenated according to the techniques of '726. For this reason, the product of instant claim 14 is patentably indistinct from the product rendered obvious by EP '985 in view of '726.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

July 9, 2010